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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/121,239 07/23/98 HARVEY

R GP091-02.UT

021365  
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HM22/0813

EXAMINER

SCHMIDT, M

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

08/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 09/121,239	<b>Applicant(s)</b> HARVEY ET AL.	
	<b>Examiner</b> Mary Schmidt	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**KATRINA TURNER**  
**PATENT ANALYST**

**Attachment(s)**

- |  |  |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                 | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)        | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 20) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

1. Claims 1-20 are pending. The claims stand rejected under 35 U.S.C. 103:
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Claim Rejections - 35 USC § 103*

3. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saunders et al. in view of Barany et al. or Reed et al. (U.S. Patent 5,908,750) for the same reasons of record as set forth in the Official Action mailed 02/28/01.

Applicant's arguments filed 05/29/01 have been fully considered but they are not persuasive.

Claim 19 was amended to recite the limitation "thereby not requiring extraction using reagents such as phenol or chloroform to prepare RNA."

Reed et al. is further cited to teach the use of "about 150 mM to about 1M of a soluble salt." See column 16, lines 42-57 where they teach use of .5M NaCl in the nuclei extraction buffer. Reed et al. is thus further cited to teach that it would be obvious to use this concentration of salt in a buffer for nuclei extraction such as the buffer claimed.

Applicants argue that since Saunders et al. and Barany et al. teach methods involving the use of phenol and chloroform that they do not read on the claimed invention.

In response the claims are broadly drawn to a method of preparing a sample containing RNA for amplification comprising the steps of (a)-(d). In view of this open "comprising"

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language, the methods of Saunders et al. and Barany et al. read on the claimed method steps. Thus, the additional steps of adding phenol and chloroform still read on the broadly claimed invention. The added limitation "thereby not requiring extraction using reagents such as phenol or chloroform" still reads on the ability to use said reagents. Just because they are not "required" does not mean that they are not still encompassed by the invention as broadly claimed.

Further, Reed was added to further teach that the claimed buffer and salt concentrations were known in the art for extraction methods such as the ones claimed in instant claims 19 and 20.

Applicant further argues that there must be a motivation in the art to combine the cited references to avoid improper hindsight reasoning. In response, a review of the art at the time the invention was made reveals a plethora of references teaching the claimed buffer concentrations. All of the cited references provide the motivation for extraction of RNA from cells. Further, Saunders et al. was found to meet the majority of the claimed limitations claimed in instant claims 19 and 20. However, in view of the fact that they do not specifically teach the claimed buffer, but instead teach use of an ionic detergent, the Barney, and now Reed references were cited as exemplary references teaching the use of the claimed salt concentrations. It was obvious at the time the invention was made to substitute one such extraction buffer having certain salt concentrations for another since the art of extraction buffers was a well-developed art and the claimed concentrations were known in the art as suitable for extraction of nucleic acids as broadly claimed.

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4. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eskola et al, Kacian et al., Saunders et al. in view of Rowley et al., Morris et al., von Lindern et al., Goddard et al., Ohki et al. and either of Barany et al. or Reed et al. for the same reasons of record as set forth in the Official Action mailed 02/28/01.

Applicant's arguments filed 05/29/01 have been fully considered but they are not persuasive.

The claims were amended to recite methods "consisting essentially of" the claimed steps and "without extracting the RNA using reagents such as phenol or chloroform". Applicants further argue as above that Barnany et al. teach use of phenol and chloroform for extraction of the nucleic acids and that the instant claimed invention does not teach such use.

In response, it was well-known in the art at the time the invention was made that phenol and chloroform were used for precipitating nucleic acids, and to separate the nucleic acids from the other cellular debris (proteins, cell-membranes, etc.) after lysis. Thus the step of phenol and chloroform is not materially significant to the claimed steps (a)-(e) of claim 1 since the claim begins with a "sample containing a first single-stranded fusion nucleic acid comprising a splice junction; (b) contacting under nucleic acid amplification conditions..." and thus does not specify what state the sample was in when first considered to be "under nucleic acid amplification conditions...". As such, the claim broadly reads on a wide range of possible samples for nucleic acid amplification which does not mention whether or not the sample was prepared with phenol and chloroform. As such, the arguments do not pertain to claims 1-5 and 9-18. In regards to

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claims 6-8, where the limitation "without extracting the RNA using reagents such as phenol or chloroform", the cited references may teach a step using phenol and chloroform, but the claims as written do not prevent one skilled in the art from using such a step despite the "consisting essentially of" language. Essentially, one skilled in the art would have recognized that phenol and chloroform were used to "clean" the nucleic acids and was not a necessary step for preparing such nucleic acids nor for "separating the hybridization complex joined to the solid support from unhybridized sample components" because use of phenol and chloroform would separate all nucleic acids, both hybridized and non-hybridized without distinguishing. The only components it would separate would be proteins from nucleic acids for instance. Thus that combination of references anticipates the claimed invention and the claims as broadly written were *prima facie* obvious at the time the invention was made.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

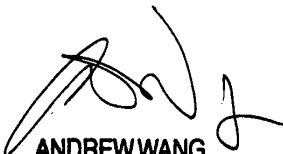
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

M. M. Schmidt  
August 12, 2001

  
**ANDREW WANG**  
**PRIMARY EXAMINER**